510(k) Summary

JUL 12 2012

Manufacture Name:	Genesis Health Light Corporation
Contact Name:	Tony Galipeau
Postal Address:	7 Innovation Drive, Hamilton, ON, L9H 7H9
Phone Number:	905 570 4102
Fax:	905 331 3108
Title:	President & CEO
Date:	May 10, 2012

Device Proprietary Name:	CS1000 Light-based heat Therapy Device
Device Common or Usual Name:	Infrared Lamp
Classification Name:	Lamp, Infrared
Classification Code:	89 ILY
Regulation Number:	21 CFR 890.5500

Predicate Devices:

Substantial equivalence is claimed to the following devices.

Name of Device	Manufacturer	Predicate Comparison	510(k) Number
Quantum WARP 10 Light Delivery System	Quantum Devices, Inc.	Intended Use, technology, materials	K032229
Narrow Band, Near-IR Energy Pain Therapy Devices	Life Without Pain, LLC	Intended Use, technology, materials	K042813

Description of the Device

Genesis Health Light's CS1000 Light-based heat Therapy Device is a hand held device used for the treatment of pain. The primary components of the device are a motor and fan, light bulb, lens and the plastic injection molded housing which encapsulates the device. Cooling liquid is located within the lens assembly. An electric cable is attached to the internal workings of the device and it plugs into a standard 120V electrical outlet to power the device.

Intended Use/Indications for Use

Genesis Health Light's CS1000 Light-based heat Therapy Device is a hand held device used for the treatment of pain by emitting energy in the near IR spectrum for the temporary relief of minor muscle and joint pain, and muscle spasm; relieving stiffness, promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Technological Characteristics

The subject and predicate devices are hand held electrical devices which utilize near infra red light therapy to relieve pain.

Substantial Equivalence Discussion

Predicate devices are the Quantum WARP 10 Light Delivery System, 510(k) K032229 and the Narrow Band, Near-IR Energy Pain Therapy Devices, 510(k) K042813. The subject and predicate devices are equivalent in terms of intended use, technology and materials.

Summary of Performance Test of Skin Surface Temperature
A performance test of skin surface temperature identified that Genesis Health Light's CS1000 device is capable of heating the skin surface to 40°-45°C. There were 7 people with light and dark skin color tone collected to measure the skin surface temperature during lighting with CS1000 device. In high power setting, the skin temperature takes 3-4 minutes to get 40°C, while 8-9 minutes when it is in low power setting. The measurement was performed every minute with a laser temperature reader till 20 minute. Over the entire test period, the temperature doesn't exceed 42°C. The skin color tone doesn't impact skin surface temperature.

Conclusion

Based on the information provided in this 510(k) premarket notification, the CS1000 Light-based Heat Therapy Device is substantially equivalent in terms of safety and effectiveness to the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Genesis Health Light Corporation
% Mr. Tony Galipeau
7 Innovation Drive Suite 102
Hamilton, Ontario,Canada L9H 7H9

JUL 12 2012

Re: K110558
Trade/Device Name: CS1000 Light Therapy Device
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: June 29 2012
Received: July 02 2012

Dear Mr. Galipeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: CS1000 Light Therapy Device

Indication for Use: Genesis Health Light's CS1000 Light Therapy Device is a hand held device used for the treatment of pain by emitting energy in the near IR spectrum for the temporary relief of minor muscle and joint pain, and muscle spasm; relieving stiffness, promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ✓ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH

Division Sign-Off
Office of Device Evaluation

510(k) K110558